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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,567	01/25/2002	Shanker Lal Gupta	214980	8884

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

5

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,567

Applicant(s)

GUPTA, SHANKER LAL

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claims 1-55 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-5 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 of copending Application No. 10056563. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Claim 1 is drawn to a compound of a given formula (1). Claim 2 is drawn to a compound of claim 1, wherein the sugar is a monosaccharide or a disaccharide. Claim 3

is drawn to a compound of claim 1, wherein the sugar is a reduced sugar. Claim 4 is drawn to a compound of claim 3, wherein the reduced sugar is mannitol or sorbitol.

Claims 6-16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 5-13, respectively, of copending Application No. 10056563. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Claims 6-16 which are further limitations of claim 1, are drawn specific compounds of the compound the given formula (1).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-51 of copending Application No. 10056563. Although the conflicting claims are not identical, they are not patentably distinct from each other because both invention are directed to the method of preparing boronic acid compound of the formula (1).

In claim 35, applicant claims "the method of preparing a lyophilized compound of the formula (1):"

Plamondon et al. claim a method of preparing a lyophilized boronic acid compound of the same general formula as the applicant (see claims 33 and 34).

The difference between applicant's claimed method and the method of Plamondon et al. is that applicant claims the use of a moiety derived from sugar. However, Plamondon et al. disclose that a compound having at least two hydroxyl groups separated by at least two carbon atoms connecting in the chains can be used (see claim 33). This implies that a moiety derived from sugar can be used, since such a sugar has the said structural and/or functional features. In fact, Plamondon et al. also disclose that the dihydroxy compound can be a sugar (see page 18, last paragraph of the specification).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method of Plamondon et al. to prepare lyophilized boronic acid compound and to use a moiety derived from sugar, since Plamondon et al. disclose that such a moiety can be used.

One having ordinary skill in the art would have been motivated, to used the method of Plamondon et al. to prepare lyophilized boronic acid compound and to use a moiety derived from sugar, since Plamondon et al. disclose that such a moiety can be used. It should noted that claims 36-49 which are further limitations of claims 35 and which are drawn to methods of preparing boronic compounds, are also encompassed by this rejection, since the prepared boronic compounds of these claims also confirm to the same general formula of the boronic compounds claimed by Plamondon et al. (example, see claims 36, 37, 38, 46, 47 (applicant) and claims 45, 46, 47, 40, 41 of Plamondon et al., respectively). Claims 50-52 which are drawn to the specific solvents, are also encompassed by this rejection since applicant uses the same solvents as Plamondon et al.

and Plamondon et al. also claim that water-miscible alcohols can be used. Claims 53 and 54 which are drawn to the method of claim 35, wherein the moiety derived from sugar and the compound of formula (3) are present in specific ratio are also encompassed by this rejection since the use of specific ratios of reactants are a matter of choice.

Claims 17-34 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-30 of copending Application No. 10056563. Although the conflicting claims are not identical, they are not patentably distinct from each other because both invention are directed to boronic acid compound of the formula (1).

In claim 17, applicant claims "a lyophilized compound of the formula (1):"

In claim 1, Plamondon et al. disclose a compound of the formula (1): In Claim 16, Plamondon et al. disclose composition comprising a compound of the formula (2) in a lyophilized powder.

The difference between applicant's claimed compound of the formula (1) and the Plamondon et al. compound of the formula (1) is that applicant claims a lyophilized form of the compound. However, Plamondon et al. claim a lyophilized composition containing the same compound (see claim 16).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a lyophilized form of Plamondon et al. compound, since Plamondon et al. disclose that the compound can be lyophilized.

One having ordinary skill in the art would have been motivated, to prepare a lyophilized form of Plamondon et al. compound, since Plamondon et al. disclose that the compound can be lyophilized. It should be noted that claims 18-32 which are further

limitations of claims 17 and which are drawn to lyophilized compounds, are also encompassed by this rejection, since the lyophilized compounds of these claims also confirm to the same general formula compounds claimed by Plamondon et al. (example, see claims 24-28 (applicant) and claims 17-25 of Plamondon et al., respectively). Claim 55, which is drawn to lyophilized cake is also encompassed by the aforementioned rejection. Claims 33 and 34 are drawn to the compound of claim 17 with specific stability at particular temperature are also encompassed by this rejection, since Plamondon et al. is silent about the stability of his lyophilized compound and such stability does not in itself limit the compound or render it different.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 4, 2003.


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200

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